hydrolyzed to the compound of formula (VIII-1). The amount of the compound of formula (VIII-1) present in the test sample is calculated from the area under the peak, on a weight to weight comparison, with the area under the peak of the reference standard. The reference standard employed is a known amount of the compound of formula (VIII-1), of known purity, which is prepared under the same conditions as the test sample. The limit of quantitation for detection of the compound of formula (I-1) is 0.2%.

[0610] To calculate the amount of compound of formula (I-1) present in a test sample, both Analytical Test Method 1 and Analytical Test Method 2 are used. Analytical Test Method 1 is used to calculate the amount on a weight basis of the compound of formula (VIII-1) that is present in a test sample, containing the compound of formula (I-1). Analytical Test Method 2 is also used to calculate the amount of the compound of formula (VIII-1) present in the sample of the compound of formula (I-1) obtained without induced hydrolysis.

[0611] The amount of the compound of formula (VIII-1) obtained from Analytical Test Method 1 minus the amount of the compound of formula (VIII-1) obtained from Analytical Test Method 2 gives the measured amount of the compound of formula (VIII-1) that is produced by the induced hydrolysis of the compound of formula (I-1) present in the test sample. Based on a 1:1 molecular ratio, a molecular weight calculation gives the amount of the compound of formula (I-1) present in the test sample.

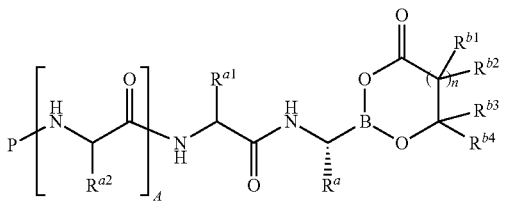
[0612] While the foregoing invention has been described in some detail for purposes of clarity and understanding, these particular embodiments are to be considered as illustrative and not restrictive. It will be appreciated by one skilled in the art from a reading of this disclosure that various changes in form and detail can be made without departing from the true scope of the invention, which is to be defined by the appended claims rather than by the specific embodiments.

[0613] The patent and scientific literature referred to herein establishes knowledge that is available to those with skill in the art. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The issued patents, applications, and references that are cited herein are hereby incorporated by reference to the same extent as if each was specifically and individually indicated to be incorporated by reference. In the case of inconsistencies, the present disclosure, including definitions, will control.

What is claimed is:

1. A process for generating a compound of Formula (II)

(II)



or a pharmaceutically acceptable salt thereof, wherein

A is 0, 1, or 2;

P is R^c—C(O)—; R^c is R^D; R^D is substituted or unsubstituted mono- or bicyclic ring system selected from the group consisting of phenyl, pyridinyl, pyrimidinyl, naphthyl, benzimidazolyl, quinolinyl, isoquinolinyl, quinoxalinyl, tetrahydroquinolinyl, tetrahydroisoquinolinyl, tetrahydroquinoxalinyl, and dihydrobenzoxazinyl;

R^a is hydrogen, C_{1-6} aliphatic, C_{1-6} fluoroaliphatic, $-(CH_2)_m-CH_2-R^B$, $-(CH_2)_m-CH_2-NHC(=NR^4)NH-Y$, $-(CH_2)_m-CH_2-CON(R^4)_2$, $-(CH_2)_m-CH_2-N(R^4)CON(R^4)_2$, $-(CH_2)_m-CH(R^6)N(R^4)_2$, $-(CH_2)_m-CH(R^{5a})-OR^{5b}$, or $-(CH_2)_m-CH(R^5)-SR^5$;

R^{a1} is hydrogen, C_{1-6} aliphatic, C_{1-6} fluoroaliphatic, $-(CH_2)_m-CH_2-R^B$, $-(CH_2)_m-CH_2-NHC(=NR^4)NH-Y$, $-(CH_2)_m-CH_2-CON(R^4)_2$, $-(CH_2)_m-CH_2-N(R^4)CON(R^4)_2$, $-(CH_2)_m-CH(R^6)N(R^4)_2$, $-(CH_2)_m-CH(R^{5a})-OR^{5b}$, or $-(CH_2)_m-CH(R^5)-SR^5$;

each R^{a2} independently is hydrogen, C_{1-6} aliphatic, C_{1-6} fluoroaliphatic, $-(CH_2)_m-CH_2-R^B$, $-(CH_2)_m-CH_2-NHC(=NR^4)NH-Y$, $-(CH_2)_m-CH_2-CON(R^4)_2$, $-(CH_2)_m-CH_2-N(R^4)CON(R^4)_2$, $-(CH_2)_m-CH(R^6)N(R^4)_2$, $-(CH_2)_m-CH(R^{5a})-OR^{5b}$, or $-(CH_2)_m-CH(R^5)-SR^5$;

each R^B independently is a substituted or unsubstituted mono- or bicyclic ring system;

each R^4 independently is hydrogen or a substituted or unsubstituted aliphatic, aryl, heteroaryl, or heterocyclyl group; or two R^4 on the same nitrogen atom, taken together with the nitrogen atom, form a substituted or unsubstituted 4- to 8-membered heterocyclyl ring having, in addition to the nitrogen atom, 0-2 ring heteroatoms independently selected from N, O, and S;

each R^5 independently is hydrogen or a substituted or unsubstituted aliphatic, aryl, heteroaryl, or heterocyclyl group;

each R^{5a} independently is hydrogen or a substituted or unsubstituted aliphatic, aryl, heteroaryl, or heterocyclyl group;

each R^{5b} independently is hydrogen or a substituted or unsubstituted aliphatic, aryl, heteroaryl, or heterocyclyl group;

each R^6 independently is a substituted or unsubstituted aliphatic, aryl, or heteroaryl group;

Y is hydrogen, —CN, or $—NO_2$;

m is 0, 1, or 2;

each of R^{b1} and R^{b2} independently is hydrogen, $—CO_2H$, —OH, or a substituted or unsubstituted aliphatic, aryl, heteroaryl, or heterocyclyl group;

each of R^{b3} and R^{b4} independently is hydrogen, $—CO_2H$, or a substituted or unsubstituted aliphatic, aryl, heteroaryl, or heterocyclyl group;

or R^{b2} and R^{b4} are each independently hydrogen, and R^{b1} and R^{b3}, taken together with the carbon atoms to which they are attached, form an unsubstituted or substituted fused 4- to 8-membered non-aromatic ring having 0-3 ring heteroatoms selected from the group consisting of O, N, and S, wherein said ring may be optionally fused to an unsubstituted or substituted 4- to 8-membered non-aromatic ring, or 5- to 6-membered aromatic ring having 0-3 ring heteroatoms selected from the group consisting of O, N, and S;